

§Appl. No. 09/684,883
Amdt. dated March 16, 2006
Reply to Office Action of, September 16, 2005

REMARKS

Entry of the attached amendment is respectfully requested. As explained in more detail below, no new issues are raised that would require further search and/or consideration.

Rejection under §102

The rejection over the Merks published patent application has been maintained, allegedly because the application discloses the claimed polypeptides. Three main reasons are set forth for not finding these arguments persuasive.

First, it is stated that claims 9-13 of Merks recite an “isolated” antigen. However, it is noted that such claims are not original claims, but were filed on 14 December 1993 to replace the original claims. Moreover, as argued previously (Response dated August 3, 2004), Merks is not enabling since, e.g., the hybridoma used to identify their polypeptide is not publicly available. Without the antibody produced by the hybridoma, Merks does not provide adequate guidance or information to identify the surface antigen, let alone isolate it. Consequently, the reference does not contain an enabling disclosure, and therefore does not anticipate the claimed invention. In his subsequent Office action, the examiner did not specifically address the enablement deficiency in the Merks publication, but instead shifted positions, arguing (in the Office action dated January 28, 2005) that the 20 kD band on the SDS-PAGE gel shown in the Merks publication would be free of any other *Neisseria* polypeptides. See, Office action, dated January 28, 2005, Page 5. Now, once again the examiner has resurrected his previous anticipation argument, but again does not address why the published patent application is enabling for an isolated 20 kD polypeptide.

In the Response dated June 28, 2005, Applicant rebutted the examiner’s contention that the 20 kD band shown in the Merks publication anticipated the claimed invention, providing evidence that it would be contaminated with other proteins. The examiner now states that

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“Consequently, even the band on the gel, with all proteins except those of the 20 kDa removed, would meet the definition of ‘isolated.’” This argument is not understood. There is nothing in the Merks publication which discloses removing “all proteins except those of the 20 kDa” polypeptide. To the contrary, the crux of Applicant’s previous argument was that the one-dimensional SDS-PAGE gels utilized in Merks to resolve the alleged 20-kDa protein would not have produced an isolated protein, nor a protein which is free of other *Neisseria meningitidis* polypeptides.

Notwithstanding such arguments, Applicant has added independent Claims 210 and 211 which recite that the claimed isolated polypeptides are free of any other *Neisseria meningitidis* polypeptide. These claims clearly distinguish over the cited Merks publication. For example, Applicant provided evidence that multiple protein species (e.g., at least the additional Spot 221 of Bernardini et al.) would have been present in the 20-kDa protein allegedly obtained by Merks in the SDS-PAGE gel. Such evidence was not found to be deficient by the examiner. Rather, the examiner chose to argue that the term “isolated” as recited in certain claims did not distinguish over it, but did not expressly address the aspects recited in Claims 187 and 189, i.e., that the isolated polypeptide is free of any other *Neisseria meningitidis* polypeptide. As such, it is believed that at least these claims are patentable.

Claims 210 and 211 do not raise new issues that would require further and/or consideration since they reflect subject matter already under consideration by the examiner. For example, Claim 210 is combination of already pending independent Claim 124 and dependent Claim 187; Claim 211 is a combination of already pending independent Claim 174 and dependent Claim 189. Thus, such subject matter has already been given consideration.

It is further stated in the Office action that “beyond the presence of the protein in the gel, Merks disclose of radioimmunoassay and ELISA’s in which monoclonal antibodies bound to the 20 kD protein.” See, Office action, Page 3. There is no indication that the ELISA procedure described on Page 9 of Merks utilizes an “isolated” antigen, rather than a mixture of antigens obtained from bacteria. This antigen mixture is absorbed to the ELISA plate, washed, and then

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incubated with antibody. Thus, the antibody bound to the antigen occurs in the *presence* of other Neisseria polypeptides. Antibodies binding to several different antigens were identified by this ELISA (See, Page 13 and Table I) procedure, further supporting the complexity of the antigen used in the ELISA procedure.

The RIA performed on Page 12 of Merks also does not result in isolated antigen. In that assay, antibody was bound to whole bacteria. See, e.g., Merks, Page 12, lines 8-13. Thus, the antigen is present on the surface of an intact bacteria.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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